NOV - 9 2000

K002503

510(k) Summary
for
Analogic Corporation
FETALGARD Lite

DATE THIS SUMMARY WAS PREPARED: August 11, 2000

SUBMITTER'S NAME AND ADDRESS:

Analogic Corporation
8 Centennial Drive
Peabody, MA 01960

CONTACT PERSON:

Steven A. Clarke, Regulatory Affairs Manager
Telephone (978)977-3000 extension 2388
Facsimile (781)245-1274

DEVICE NAME:

Proprietary Name:	FETALGARD Lite
Common Name:	Fetal Monitor
Classification Name:	Perinatal Monitoring System

PREDICATE DEVICE:

The legally marketed device to which equivalence is being claimed is:

FETALGARD 3000 Fetal Monitor cleared under premarket notification K983395.

DEVICE DESCRIPTION:

The FETALGARD Lite System consists of the monitor itself, single or twins ultrasound transducer, tocotonometer, a separate power supply, and optional chart recorder.

Uterine contractions are monitored using an external tocotonometer.

K002503

Fetal heart rate is measured using an external pulsed Doppler ultrasound transducer.

Heart rate, and uterine activity are presented graphically on an LCD display or chart recorder.

The FETALGARD Lite is intended for Antepartum applications that do not require the invasive features of intrauterine pressure and fetal scalp ECG.

INTENDED USE:

The FETALGARD Lite is a Perinatal Monitoring System for non-invasively measuring and showing graphically maternal abdominal contractions and the fetal heart rate by means of display on a non-permanent graphical display and optionally on a strip chart recorder. This data is intended to aid in assessing the well being of the fetus during the final trimester of pregnancy (Non-Stress Test). This device is for use only by trained medical personnel located in hospitals, clinics, doctors' offices and in the patient's home.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The FETALGARD Lite is a Non-Invasive Fetal Monitor that is based a subset of features and components of the FETALGARD 3000 Fetal Monitor that was cleared for marketing under Premarket Notification K983395.

For those features that are common to the two devices, a new detail hardware design implements equivalent performance specifications, using the same principal of operation and updated materials and manufacturing techniques.

The software algorithms have been ported from the Intel processor in the predicate device to the Motorola processor in the new device. The new implementation meets or exceeds the current specifications and simulation testing demonstrates equivalent performance.

The user interface has been modernized to improve ease of use.

NONCLINICAL TESTS USED IN DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The new device has undergone verification and validation test scenarios to show that all functions are in compliance with the user requirements, safety standards, and performance specifications. This involved the use of both simulated input signals and tape recordings of actual physiological waveforms.

K002503

The system has been tested for electrical safety according to IEC 60601-1, electromagnetic compatibility according to IEC 60601-1-2, and biocompatibility according to ISO 10993-1.

CONCLUSIONS FROM NONCLINICAL TESTING:

The testing of the FETALGARD Lite demonstrates the performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 9 2000

Steven A. Clarke, RAC
Regulatory Affairs Manager
Analogic® Corporation
Corporate Regulatory Affairs
8 Centennial Drive
PEABODY MA 01960

Re: K002503
Analogic FETALGARD Lite Fetal Monitor
Dated: August 11, 2000
Received: August 14, 2000
Regulatory Class: II
21 CFR §884.2740/Procode: 85 HGM

Dear Mr. Clarke:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002503

Device Name: FETALGARD Lite

Indications For Use:

The FETALGARD Lite is a Perinatal Monitoring System for non-invasively measuring and showing graphically maternal abdominal contractions and the fetal heart rate by means of display on a non-permanent graphical display and optionally on a strip chart recorder. This data is intended to aid in assessing the well being of the fetus during the final trimester of pregnancy (Non-Stress Test). This device is for use only by trained medical personnel located in hospitals, clinics, doctors' offices and in the patient's home.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE ~~IF NECESSARY~~)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002503